IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC., *Plaintiff*, v. SAVE ON SP LLC, *Defendant*.	Case No. 2:22-cv-02632-JMV-CLW

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF

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INTRODUCTION

Amicus Pharmaceutical Research and Manufacturers of America (PhRMA) is an association representing the country's leading biopharmaceutical companies, which develop and manufacture innovative medicines and treatments that patients depend on to save or improve the quality of their lives. Many of PhRMA's members offer financial assistance to commercially insured patients to help them afford these treatments in the face of rising cost-sharing obligations imposed by their health plans to access prescription medications. High cost-sharing amounts discourage patients from accessing or adhering to essential medications that their doctors have prescribed. Patient assistance programs like the one run by Johnson & Johnson Health Care Systems (JJHCS) for commercially insured individuals assist with such cost-sharing burdens. Research shows that through these programs, manufacturers defray patients' out-of-pocket costs and help them access or adhere to their prescribed treatments, improving health outcomes for those patients and generating savings for the healthcare system and the public.

Schemes like SaveOnSP's so-called "maximizer programs" threaten to make these critical manufacturer assistance programs unsustainable. Although manufacturers intend for their financial assistance to help commercially insured patients pay for their out-of-pocket costs, schemes like SaveOnSP's extract funds from these programs to unjustly enrich themselves. By design, maximizer programs

like SaveOnSP's induce health plans to alter benefits solely to avoid the patient cost-sharing limitations required by the Affordable Care Act (ACA) and then create artificial, variable cost-share requirements to drain manufacturer assistance provided to commercially insured patients faster and to a greater extent than a health plan without a maximizer program otherwise would. Maximizer programs therefore jeopardize the existence of the manufacturer assistance programs and the benefits they provide to patients.

SaveOnSP wrongly argues that its scheme does not cause harm. Mot. to Dismiss at 16–18, 22–25. But the injuries maximizer programs inflict on affected patients, the public, and pharmaceutical manufacturers are readily apparent. Maximizer programs make patient assistance significantly more expensive for manufacturers to provide and artificially drain the funds available to commercially insured patients for their cost-sharing amounts, contrary to the terms and conditions applicable to manufacturer assistance programs. If schemes like SaveOnSP's succeed in draining manufacturer assistance funds for the benefit of entities like SaveOnSP rather than the patients for whom the assistance is intended, then patients may ultimately lose the assistance manufacturers now provide, and with that, access to essential medications. Furthermore, these harms to patients and the public could lead to worse health outcomes and an associated rise in healthcare costs.

ARGUMENT

I. MAXIMIZER PROGRAMS LIKE SAVEONSP'S CAUSE HARM TO PATIENTS, THE PUBLIC, AND DRUG MANUFACTURERS.

A. Manufacturer Cost-Sharing Assistance Programs Help Patients Access and Afford Necessary Medications and Improve Health Outcomes.

Under many commercial health insurance plans, patients are subject to high cost-sharing obligations for their prescription medications. Between 2012 and 2017, the share of employer-sponsored health plans with a deductible for prescription drugs more than doubled, to 52% from 23%. PhRMA, *Faced with High Cost Sharing for Brand Medicines, Commercially Insured Patients with Chronic Conditions Increasingly Use Manufacturer Cost-Sharing Assistance* 3 (Jan. 29, 2021) (PhRMA 2021);[1] *see* Compl. ¶ 40. These deductibles can often become unaffordable for patients and their families when faced with the overall cost of care and disease impact on the patient's life. In 2019, average annual deductibles for family coverage ranged from almost $3,000 for employer-sponsored health plans to over $13,000 for some plans available on health insurance exchanges. PhRMA 2021 at 3. Moreover, once a plan's deductible is met, a patient may face coinsurance obligations as high as 30% to 50%. *Id.*

[1] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Faced-with-High-Cost-Sharing-for-Brand-Medicines.pdf.

Research shows that as cost-sharing burdens on patients rise, patients become more likely to abandon their prescriptions at the pharmacy. According to one study highlighted in the Complaint, over half of patients who learned that they would owe between $125 and $250 for a prescription medication did not start the therapy; and 69% of patients did not even begin taking a medication if the patient cost-share was greater than $250. *See* Katie Devane et al., *Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption*, IQVIA 1 (2018) (Devane, *Patient Affordability*);[2] *see* Compl. ¶ 41. Further, decades of research demonstrates that "an increasing patient share of medication costs [i]s significantly associated with a decrease in adherence" to a therapy over time. Michael T. Eaddy et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes*, PHARMACY & THERAPEUTICS 45 (Jan. 2012) (surveying studies since the 1980s);[3] *see* Compl. ¶ 41.

Predictably, patients who are unable to access the treatments prescribed by their doctors experience worse health outcomes. *See, e.g.*, Aurel O. Iuga & Maura J. McGuire, *Adherence and Healthcare Costs*, 7 RISK MGMT. HEALTH CARE POL'Y 35 (Feb. 2014);[4] *see* Compl. ¶ 42. Nonadherence is also associated with billions of

[2] https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two.
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/.
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/.

dollars in avoidable healthcare costs connected to disease progression and doctor's visits and hospitalizations. *Id.*

To support patient access, pharmaceutical manufacturers like JJHCS provide essential cost-sharing financial assistance to patients enrolled in commercial insurance. By one estimate, pharmaceutical companies offered $14 billion in assistance in 2020 alone. Tomas J. Philipson et al., *The Patient Impact of Manufacturing Copay Assistance in an Era of Rising Out-of-Pocket*, U. CHI. 2 (Dec. 2021) (Philipson, *Patient Impact*);[5] Compl. ¶ 22 n.5. This assistance is designed to help patients initiate and continue taking their prescribed medications and takes the form of programs providing patients with coupons, copay cards, or rebates applied at the point of sale to the patient's cost-sharing obligations. Compl. ¶ 44. The assistance is offered pursuant to certain terms and conditions agreed to by the patient and the manufacturer. *See id*. ¶¶ 18–20, 48, 89, 103.

Although this manufacturer assistance is indispensable to commercially insured patients taking a wide range of medications, patients with complex or chronic illnesses are particularly reliant on manufacturer assistance programs. PhRMA 2021 at 6–7; Philipson, *Patient Impact* at 8. These patients, who suffer from illnesses like cancer, rheumatoid arthritis, and HIV, often depend on specialty drugs

[5] https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/12/2021_12_15-Copay-Assistance-Final-Draft-Clean.pdf.

that tend to cost more because they require careful handling and, due to their complexity, are difficult to manufacture and develop. *Id.* Many patients need these drugs to improve their quality of life or save their lives. *Id.* Yet patients with these diseases are increasingly subject to especially large coinsurance obligations for their specialty medications. PhRMA 2021 at 5. As a result, in 2019, for example, about a third of patients filling brand-name oncology medicines used manufacturer cost-sharing assistance, as did 70% of patients filling brand-name multiple sclerosis (MS) medications. *Id.* at 6.

Research indicates that manufacturer patient assistance programs significantly enhance the ability of these and other patients to fill their prescriptions. Manufacturer cost-sharing assistance saved patients prescribed brand HIV and oncology medicines an average of over $1,600 out of pocket in 2019, and patients taking brand MS medicines received more than $2,200 toward their out-of-pocket costs that same year. *Id.* at 7; *see also* Philipson, *Patient Impact* at 7–8 (finding that manufacturer assistance saved patients $12 billion out of pocket in aggregate in 2019). As a result of these savings, patients are better able to access and adhere to their treatments. One study found that patients with cost-sharing assistance picked up one brand-name prescription from the pharmacy over 20 days faster than patients without assistance, and that patients with assistance were at 88.2% lower risk of abandoning their first prescription and at 24.3% lower risk of discontinuing

treatment over the first year. Philipson, *Patient Impact* at 12 n.16 (discussing A. Seetasith et al., *The impact of copay assistance on patient out-of-pocket costs and treatment rates with ALK inhibitors*, 22 J. MED. ECON. 414 (2019)).

By helping patients afford and, therefore, access the drugs their doctors prescribe, manufacturer cost-sharing assistance programs also improve patient health. Unsurprisingly, patient adherence to doctor-prescribed medication regimens is associated with improved health outcomes, and adherence saves the healthcare system and the public money down the line, by avoiding preventable disease progression and unnecessary doctor's visits and hospitalizations. Philipson, *Patient Impact* at 10–16. According to one analysis, manufacturer assistance programs are associated with up to a 3.3% improvement in overall health outcomes and save the healthcare system between $8.1 and $29 billion in "medical services linked to worse health outcomes." *Id.* at 4, 10.

B. Maximizer Programs Siphon Off Manufacturer Assistance Funds Intended for Patients to Enrich Third Parties.

In recent years, schemes like SaveOnSP's have arisen to co-opt funds intended to benefit commercially insured patients. For example, third-party companies have worked with many commercial insurers to implement "accumulator adjustment programs" that track when a patient uses manufacturer assistance and then decline to count the value of that assistance toward the patient's deductible or the ACA's annual limit on cost sharing. Adam J. Fein, *Copay Maximizers Are*

Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support, DRUG CHANNELS (May 19, 2020) (Fein, *Copay Maximizers*);[6] Compl. ¶ 50 n.7. As a consequence, the patient could be delayed in reaching the health plan's deductible or cost-sharing maximum, and the patient could pay the full cost of the drug eligible for manufacturer assistance, as well as the full cost of other drugs, for longer. *Id.* Accumulator adjustment programs thus frustrate the purpose of caps on out-of-pocket costs imposed by law. Moreover, research has found that accumulator adjustment programs harm patients, for example, by decreasing their adherence to therapies. *See* Fein, *Copay Maximizers* (citing a 2019 study). Thus, sixteen states have passed legislation banning or heavily restricting these programs.[7]

Increasingly, companies like SaveOnSP are offering a new type of program referred to as a "maximizer," whereby the patient's out-of-pocket cost for a manufacturer-assistance eligible drug is set at number that is inflated based on the availability of manufacturer assistance—*not* based on the patient's medical need or

[6] https://www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html.
[7] ARIZ. REV. STAT. ANN. § 20-1126; ARK. CODE ANN. § 23-79-2103; CONN. GEN. STAT. §§ 38a-477ff, -477gg, -478w; DEL. CODE. ANN. 18, §§ 3555A, 3566A; 3381A; GA. CODE ANN. § 33-64-10; 215; ILL. COMP. STAT. 134/30; KY. REV. STAT. ANN. § 304.17A-164; LA. STAT. ANN. § 22:976.1; ME. REV. STAT. ANN. 24-A, § 4349; N.C. GEN. STAT. § 58-56A-3; OKLA. STAT. tit. 36, § 1250.5 (18); TENN. CODE ANN. § 56-7-3205; VA. CODE ANN. § 38.2-3407.20; WASH. REV. CODE § 48.43.435; W. VA. CODE §§ 33-15-4t, 33-16-3ee & 33-25A-8t. Note that New York's legislation (S5229A/A1741-A) prohibiting accumulator adjustment programs or copay accumulators was passed on May 24, 2022, but the legislation has not yet been signed into law as of August 17, 2022.

the price of the drug. *Id.* Patients are then informed that they can avoid these artificially high cost-sharing obligations by enrolling in a "savings" program run by a third-party company (such as SaveOnSP) that specializes in running maximizer programs. *See id.*

However, maximizer programs do not generate real savings for patients. Instead, companies such as SaveOnSP that offer these programs purportedly facilitate the patient's signing up for the manufacturer cost-sharing assistance program that is already available to the patient. *See id.* If a patient does not enroll, the patient must pay an inflated cost-sharing obligation. *Id.* For example, SaveOnSP threatens the patient "by telling them that they will either pay $0 per prescription if they enroll, or will have to pay the inflated copay cost … themselves if they do not." Compl. ¶ 60. And even if the patient does enroll, the payments from the manufacturer assistance program do not count toward the patient's deductible or out-of-pocket maximum, meaning that the patient will pay more for other healthcare services across the plan year. *Id.* ¶ 78. As the Complaint aptly summarizes, "[b]y changing the amounts owed by patients based on only the availability of patient assistance, the programs disconnect patient assistance from actual cost to patients, causing patient assistance programs to be more expensive than originally intended, and converting what is meant to be patient assistance into a manufacturer subsidy" for SaveOnSP and payers. *Id.* ¶ 74.

As described in the Complaint, SaveOnSP's particular scheme works by designating drugs that are eligible for manufacturer assistance as "non-essential health benefits" under the ACA—*without* regard for how essential a drug is to patients' health and wellbeing. *Id*. ¶¶ 9–10, 53–54, 57–60. This ploy skirts the ACA's annual limitations on the out-of-pocket costs that plans are required to adhere to when offering essential health benefits; in turn, the ploy makes it possible to artificially "inflat[e]" patients' cost-sharing requirements for the drug. *Id.* ¶¶ 8, 12, 56 (quoting SaveOnSP presentation). SaveOnSP then uses the coercive methods alleged in the Complaint to induce patients to sign up for its program, including telling patients that if they do not participate in its program, their cost-sharing obligation will equal the increased amount. *Id.* ¶¶ 60–63. Yet SaveOnSP's program does not itself reduce the patient's costs or create any real savings for the patient. *Id.* ¶ 64. Instead, once a patient agrees to enroll, SaveOnSP facilitates signing the patient up for the manufacturer assistance for which the patient would be eligible without SaveOnSP, fundamentally disrupting the intended use of the manufacturer program (that is, independently by the patient) and violating the terms and conditions of the manufacturer's program. SaveOnSP's offer to patients thus represents a Hobson's choice: pay an inflated price for the prescription or violate the terms and conditions of the manufacturer's assistance program by taking part in SaveOnSP's scheme.

C. Programs like SaveOnSP's Threaten to Destroy Patient Assistance Programs to the Detriment of Patients, the Public, and Drug Manufacturers.

Schemes like SaveOnSP's maximizer programs artificially drain manufacturer assistance programs for commercially insured patients in violation of the terms and conditions of those programs and could ultimately make these programs unfeasible. Because maximizer programs artificially inflate patients' out-of-pocket cost obligations for a drug by indexing those obligations to the amount of financial assistance available from the manufacturer for that drug, manufacturers must pay out more to achieve the intended cost-sharing assistance than they otherwise would. Patient assistance programs thus become prohibitively expensive for pharmaceutical companies, and particularly for small pharmaceutical companies, to operate. *See Id*. ¶ 22

Here, for example, the Complaint estimates that SaveOnSP causes JJHCS to spend thousands of dollars more per patient each year than it otherwise would. *Id*. ¶¶ 92–99 (providing data). As alleged in the Complaint, JJHCS has paid at least *$100 million* that it would not have paid had SaveOnSP not succeeded in artificially inflating the amounts that plans charge for drugs. *Id.* ¶ 5. As SaveOnSP itself acknowledges, these losses are directly traceable to its activities. *See* Mot. to Dismiss at 11, 13 (arguing that the scheme would not exist without SaveOnSP's activities). And the additional funds manufacturers expend ultimately line the pockets of

SaveOnSP and its partners; the funds do not benefit patients, who could use manufacturer assistance absent a maximizer program like SaveOnSP's. The losses traceable to maximizer programs could be difficult for manufacturers to sustain over time, and this difficulty will be especially pronounced for small pharmaceutical companies that may offer a patient assistance program covering one or two products.

The destruction of manufacturers' assistance programs would harm commercially insured patients. Due to cost-sharing obligations imposed by plans, patients depend on these programs to access and adhere to the medication therapies that their doctors have prescribed for them. *See supra*, at 7–8; Compl. ¶¶ 22, 114. Without manufacturer help to meet their insurance cost-sharing obligations, patients would abandon or discontinue these therapies at higher rates. One analysis concluded that if manufacturer cost-sharing assistance had not been available between 2014 and 2017, new patient abandonment rates would have been between 12% and 19% higher. Devane, *Patient Affordability* at 2. When patients do not use the medications that their doctors prescribe for them, they are at increased risk of disease progression and of requiring more inpatient and outpatient medical care. *See supra*, at 4–5,6–7.

This harm to patients would hurt the healthcare system and the public as well. Patients who are unable to adhere to the medication regimens their doctors prescribe ultimately burden the healthcare system and the public with billions of dollars in

avoidable medical costs. *See id*. And if programs like SaveOnSP succeed in making cost-sharing assistance unsustainable, the billions of dollars in healthcare cost savings currently generated by those assistance programs would be erased.

CONCLUSION

Maximizer schemes like SaveOnSP's cause harm to patients, to the public, and to drug manufacturers like JJHCS and PhRMA's members that offer patient assistance programs. The Court should reject SaveOnSP's arguments to the contrary and deny the motion to dismiss.

Dated: August 18, 2022

Respectfully submitted,

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